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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,194	07/07/1999	KENNETH F. BUECHLER	244/121	6285

23620 7590 08/18/2003

FOLEY & LARDNER  
402 WEST BROADWAY  
23RD FLOOR  
SAN DIEGO, CA 92101

EXAMINER
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GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/18/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Applicati n No.

09/349,194

Applicant(s)

BUECHLER ET AL.

Examiner

Gailene R. Gabel

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 07 July 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
4. ☒ Newly proposed or amended claim(s) 134-138 and 140-142 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 134-138 and 140-142.Claim(s) objected to: 114-118 and 139.Claim(s) rejected: 85-96, 102-106, and 119-133.Claim(s) withdrawn from consideration: NONE.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's response filed 7/7/03 in Paper No. 27 is acknowledged and has been entered. Currently, claims 85-96, 102-106, and 114-142 are pending.

### **Claim Objections**

2. Claims 114-118 and 139 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 102-106 and 138, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### **Rejection Maintained**

3. Claims 85-96, 102-106, and 119-133 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a cocktail of antibodies, each having specific binding for free cTnI, binary complex of cTn, and ternary complex of cTn for use in an assay for determining free and complexed cardiac specific isoforms of troponin (cTn) using, does not reasonably provide enablement for an antibody, i.e. single monoclonal antibody, having specific binding for each and all of free cTnI, binary

Art Unit: 1641

complex of cTn, and ternary complex of cTn for use in an assay for determining free and complexed cTn. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

### ***Response to Arguments and Declaration***

4. Applicant's arguments filed 7/7/03 have been fully considered but they are not persuasive.

Applicant contends that Examiner has not established any reasonable basis for questioning enablement of the rejected claims and has improperly dismissed additional evidence supporting enablement provided in the form of an opinion declaration by Dr. Kenneth Buechler encompassing a reasoned scientific explanation as to why the skilled artisan could practice the instantly claimed invention without undue experimentation. According to Applicant, a considerable amount of experimentation is permitted provided that the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

In response to Applicant's statements in the declaration provided by Dr. Kenneth Buechler describing that those of ordinary skill in the art would readily acknowledge that the claimed antibody can be produced using only routine methods well known in the art, it is well established that even though level of skill and knowledge in the art at the time of filing was such that production of antibodies against a well characterized antigen such as troponin is well known and conventional, Applicant has not demonstrated nor

Art Unit: 1641

has he provided sufficient guidance, that a particular conclusory antibody that identifies that conserved epitope that is universal to all of the cardiac specific isoforms of troponin such as claimed is known, well-characterized, or sequenced so as to enable the claimed invention. To reiterate, the specification provides general teaching of how such antibody can be generated, selected, and used. Applicant's opinion declaration, likewise, provides description and clarification of how such an antibody can be selected based on its binding to a cardiac specific region that is present and presumably accessible in any of the free, binary, and ternary forms of troponin, but does nothing to further enable the claimed single antibody, i.e. single monoclonal antibody, having specific binding for a universal epitope present and accessible in each and all of free cTnI, binary complex of cTn, and ternary complex of cTn, for use in an assay for determining all of the free and complexed cardiac specific isoforms of cTn. As such, Applicant's statements in the declaration that such antibody can be generated and in existence so as to render Applicant's possession of the claimed antibody, are prophetic and speculative but not convincing.

***Allowable Subject Matter***

5. Claims 134-138 and 140-142 are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703)

Art Unit: 1641

305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641

*gg* 8-13-03

*Christopher L. Chin*

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641